#25/K.T. 11/13 Elect.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF MAILING

I hereby certify that this RESPONSE TO PTO ACTION - RESTRICTION REQUIREMENT and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date indicated below with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

OFFICIAL

Ariel Fletcher

6/27/2003
Date of Deposit

Applicant: Joyce, et al.

Serial No.: 09/423,035

Filed: January 13, 2000

Title: ENZYMATIC DNA MOLECULES

Group Art Unit: 1635

Examiner: K. Lacourciere

Our Ref.: TSRI 463.4

RESPONSE TO PTO ACTION - RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This communication is in response to the PTO Action requiring further restriction mailed March 31, 2003 (Paper No. 23). The response is filed with a two month extension of time and required fee but before reduction of any earned patent term adjustment.

Applicants previously elected group I having claims 1-22 and 25-46, with claims 23 and 24 withdrawn from consideration as being drawn to a nonelected invention. The Examiner has issued the present Action requiring further restriction as the application allegedly contains inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner contends that the international searching authority considers that the present international application, a national stage application, does not comply with the requirements of unity of invention (Rules 13.1, 13.2, and 13.3). Specifically, the Examiner states that the claims are directed to catalytic DNA molecules with two different stem structural motifs, Formula I and Formula II (SEQ ID NO 122) and different structures, SEQ ID NO 102-121. The Examiner states that the latter sequences functionally target different RNA substrates, different regions

within an RNA, and different regions within the same RNA, and inhibit the expression of different proteins or cleave a target protein to a different degree.

Before addressing the issue of the alleged lack of unity of invention of the claimed catalytic DNA molecules that are subject to restriction, Applicants request that the record be rectified as to what the Examiner has included as a claimed catalytic DNA molecule. Therefore, Applicants direct the Examiner's attention to the application at page 92, lines 23-33, continuing to page 93, lines 1-7, then including Table 4, page 93, lines 10-31, continuing to page 94, lines 1-4. At the noted pages and lines, the specification describes that the 10-23 catalytic DNA enzyme was used to cleave a variety of biologically relevant RNAs. Synthetic RNA substrates of the translation initiation sites were prepared from HIV-1 gag/pol, env, vpr, tat, nef, FIV gag, IGF-R, and E100 ligase. The synthetic RNA substrates listed in Table 4 are identified with sequence listing identifiers from SEQ ID NOs 102-119. These were subjected to cleavage by only the 10-23 catalytic DNA enzyme. Thus, they are substrates and have been mischaracterized by the Examiner as being catalytic DNA molecules subject to further restriction practice. The Examiner has, however, correctly identified the sequences listed as SEQ ID NOs 120, 121 and 122 as catalytic DNA molecules, respectively, 8-17, 10-23 and Formula II. Consequently, the record should reflect that the sequences subject to restriction are only SEQ ID NOs 120, 121 and 122.

In view of the foregoing, the Examiner's restriction requirement at the bottom of page 3 of the Action should be amended to correctly state that the Applicant must elect a single catalytic DNA molecule, SEQ ID NO 120 or 121, and one corresponding stem Formula, I or II (SEQ ID NO 122).

In response to the Examiner's restriction requirement limited by the foregoing, Applicants elect, with traverse, SEQ ID NO 121, corresponding to the catalytic DNA molecule identified as 10-23, and the corresponding Formula II (SEQ ID NO 122).

Applicants response and arguments for traversal of the present Action therefore continues below based on the limitations in the previous paragraph limiting the catalytic DNA molecules subject to restriction to SEQ ID NOs 120 and 121 and Formulas I and II.

In electing with traverse, Applicants cite to MPEP §1850 in which unity of invention of nucleotide sequences is discussed. As stated in paragraph 2, "The PCT permits inventions that

lack unity of invention to be maintained in the same international application for payment of additional fees. Thus, in international applications, for each group for which applicant has paid additional international search and/or preliminary examination fees, the USPTO has determined that up to four (4) such additional sequences per group is a reasonable number for examination. Further, claims directed to the selected sequences will be examined with claims drawn to any sequence combinations which have a common technical feature with the selected sequences."

Applicants enclose a copy of the PCT International Preliminary Examination Report (Exhibit I) for the present claims. The box, identified as Box IV, for lack of unity of invention was not checked. As such, Applicants contend that the Examiner is incorrect in stating on page 3 of the Action that "unity of invention between the catalytic DNA sequences is lacking as each sequence claimed is considered to constitute a special technical feature." Had the International Report indicated a lack of unity of invention, Applicants would have paid additional search fees that would have allowed up to four additional sequences to be examined. But because Box IV was not checked, Applicants did not have a basis or a need for paying additional search fees. In view of these facts, Applicants assert that the Formulas I and II and their respective species, 8-17 and 10-23, do not exceed the reasonable number of sequences that can be reasonably examined. Moreover, Applicants contend that the claims recite sequences which have a common technical feature. Specifically, the technical features linking the Formulas I and II are the presence of first and second substrate binding regions that flank a core region. In addition, as stated on specification page 87, lines 3-7, the enzymes, 10-23 and 8-17, are generic enzymes which can cleave any preselected target sequence, and that target specificity depends solely on the sequence of the substrate binding regions of the enzyme. Therefore, Applicants assert that a second basis for overcoming an alleged lack of unity of invention is the presence of technical features linking the claimed Formulas I and II, thereby allowing all the claimed sequences to be examined and not be subject to further restriction.

The Examiner also argues that the present claims reciting Formulas I and II are Markush group compounds that do not meet the requirements for unity of invention. Under MPEP §803.02, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that

utility. MPEP §803.02 also states that it is "improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." The catalytic DNA enzymes encompassed by the present claims (1) share the common utility of being able to cleave any preselected target sequence and (2) share substrate binding regions that are essential to that utility. Moreover, MPEP §803.02 also states that if the members of the Markush group are sufficiently few in number, which is two in the present case, or so closely related, which is true in this case, that a search and examination can be made without serious burden, then the Examiner must examine all the members of the Markush group in the claim on the merits, even if they might be directed to independent and distinct inventions.

In view of the all the foregoing reasonable arguments, Applicants assert that traversal of the present Action is appropriate and respectfully requests that the Examiner reconsider the present Action and requirement for a further election of one Formula and one species under the Formula. Applicants respectfully request entry of the above-identified response to the Action.

Respectfully submitted,

6-27-03
Date

Emily Holmes, Reg. No. 40,652

THE SCRIPPS RESEARCH INSTITUTE
Office of Patent Counsel
10550 North Torrey Pines Road
Mail Drop TPC-8
La Jolla, California 92037
(858) 784-2937

P:\Emily\WP\OA\SCR2190P.RR2